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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,270	07/25/2005	Corrado Spadafora	27419/200	9338

7590 06/17/2010

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EXAMINER	
KANTAMNENI, SHOBHA	

ART UNIT	PAPER NUMBER
1627	

MAIL DATE	DELIVERY MODE
06/17/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/500,270	SPADAFORA ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1627	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 May 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *NONE*.
   Claim(s) objected to: _____.
   Claim(s) rejected: *3-5,7-9,12 and 13*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See page 2.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627

Continuation of 3. Applicant's proposed amendment which amended claims herein, especially claim 3 (the independent claim), by changing limitations and the scope of claims, present a new issue for search and consideration by the Examiner. Therefore, the proposed amendment After Final will not be entered.

Continuation of 11 . All rejections of record in the Final Office Action 03/01/2010 are maintained in view of the proposed amendment After Final not entered. Applicant's remarks/arguments filed on 05/27/2010 after FINAL with respect to all rejections made have been fully considered but are unpersuasive in view of not entered proposed amendment, and those found below.

Rejection of Claims 3, 4, 7 under 35 U.S.C. 103(a) as being unpatentable over Grimaudo et al. (European Journal of Cancer, vol. 34, pages 1756-1763, 1998, PTO-1449).

Applicant argues that "one of ordinary skill in the art would not have generalized that NNRTI would have been useful for treating leukemia based on the teachings of Grimaudo. One reason for this is the fact that TBZ has a completely different structure from the compounds recited in claim 3. Neither nevirapine, efavirenz, delaviridine, nor 5,11-dihydro-6H-dipyrido-(3,2-b:2',3'- e)(1,4)-diazepine compounds are thiazolo benzimidazoles like TBZ." These arguments have been considered, but not found persuasive. It is pointed out that though TBZ and instant compound have different structures, they are functionally equivalent as non-nucleoside reverse transcriptase inhibitors. Accordingly, one would have had an expectation of similar success in treating leukemia with a specific non-nucleoside reverse transcriptase inhibitor, efavirenz, as instantly claimed because Grimaudo et al. render the administration of non-nucleoside reverse transcriptase inhibitor to treat leukemia obvious.

Regarding, Applicant argument that the the anti-tumor effect of TBZ on HL60 tumor cells is not related to its RT inhibitory activity, it pointed out that nowhere does Grimaudo et al. teach that anti-tumor effect of TBZ is not related to RT inhibitory activity. Applicant's arguments merely presents statements, conclusion or speculations or opinions regarding the mechanism, but fails to set forth any factual evidences.

Rejection of Claims 3, 4, 5, 12-13 under 35 U.S.C. 103(a) as being unpatentable over Ghori et al. (Colorectal Disease, 2000, 2(2), pages 106-112, PTO-1449).

Applicant argues that " Ghori speculates that nucleoside analogues (but not NNRTIs) may be useful as agents for the treatment of colorectal cancers (see Ghori at p. 111). Even assuming this to be true, which applicants do not admit, then Ghori cannot be said to support treating even colorectal cancers with a different class of agents (the NNRTIs recited in claim 3) that are structurally distinct. " These arguments have been considered, but not found persuasive because Ghori broadly teaches that the purpose of their study was to determine the degree of inhibition of retroviral reverse-transcriptase inhibitors in treating colorectal cancer by inhibiting telomerase activity, and provides examples with nucleoside reverse-transcriptase inhibitors. Ghori et al. also teaches broadly that drugs useful to inhibit RT (exemplified by HIV RT) should effectively inhibit telomerase. Accordingly, it would have been obvious to a person of ordinary skill in the art at the time of invention to employ other retroviral reverse-transcriptase inhibitors such as instant NNRTI with reasonable expectation of success of treating colorectal by inhibiting telomerase activity.